**QUESTIONS FOR PANEL:**

- Does the petitioner's proposed classification sufficiently describe constrained hip devices? If not, what other types of descriptive information should be included in the classification definition for constrained hip devices?

- Based on the known clinical information, for which patient populations should constrained hip devices be indicated?

- For constrained hip devices, medical device reports (MDRs) have identified clinical and technical problems, including:

  Dislocation, Disengaged Liner, Ring Broken, Ring Migration, Revision, Cement Loosening, Broken Insert (Implant), Tapers Unlocked, Liner Wear, Size Mislabeled, Device Split, Poor Liner Fit, and Ring Wouldn't Fit.

  From the literature and MDRs, have all the risks to health for constrained hip devices been adequately addressed? If not, what additional risks should be described?

- The original classification included devices to be fixed with or without bone cement but excluded devices intended for biological fixation. What impact does the means of fixation have on constrained designs (e.g., cemented, hydroxyapitite coated, porous coated, press-fit)? Has the petitioner provided sufficient information to reclassify devices intended for cemented, uncemented, and/or biological fixation?